

IDS Form PTO/SB/08: Substitute for form 1449A/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Application Number	10/623,431
				Filing Date	July 18, 2003
				First Named Inventor	Jay D. KRANZLER
				Art Unit	1614
				Examiner Name	Alicia R. HUGHES
Sheet	1	of	4	Attorney Docket Number	11013.0012-00000

U.S. PATENTS AND PUBLISHED U.S. PATENT APPLICATIONS					
Examiner Initials ¹	Cite No. ¹	Document Number	Issue or Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
/AH/	1	4,708,834	11-24-1987	COHEN	
/AH/	2	4,710,384	12-01-1987	ROTMAN	
/AH/	3	4,734,285	03-29-1988	ALDERMAN	
/AH/	4	4,740,198	04-26-1988	THEEUWES	
/AH/	5	4,756,911	07-12-1988	DROST, et al.	
/AH/	6	4,761,501	08-12-1988	HUSBANDS, et al.	
/AH/	7	4,775,535	10-04-1988	LOWEY	
/AH/	8	4,781,919	11-01-1988	LIEBOWITZ	
/AH/	9	4,784,858	11-15-1988	VENTOURAS	
/AH/	10	4,792,448	12-20-1988	RANADE	
/AH/	11	4,795,327	01-03-1989	GAYLORD, et al.	
/AH/	12	4,795,642	01-03-1989	COHEN, et al.	
/AH/	13	4,795,645	01-03-1989	FRIEDMAN, et al.	
/AH/	14	4,798,725	01-17-1989	PATEL	
/AH/	15	4,800,083	01-24-1989	HOM, et al.	
/AH/	16	4,803,076	02-07-1989	RANADE	
/AH/	17	4,803,079	02-07-1989	HSAIO, et al.	
/AH/	18	4,806,359	02-21-1989	RADEBAUGH, et al.	
/AH/	19	4,816,262	03-28-1989	MCMULLEN	
/AH/	20	4,820,522	04-11-1989	RADEBAUGH, et al.	
/AH/	21	4,822,619	04-18-1989	EICHEL, et al.	
/AH/	22	4,824,678	04-25-1989	LINDAHL, et al.	
/AH/	23	4,832,957	05-23-1989	DEMPSKI, et al.	
/AH/	24	4,837,032	06-06-1989	ORTEGA	
/AH/	25	4,842,866	06-27-1989	HORDER, et al.	
/AH/	26	4,849,229	07-18-1989	GAYLORD, et al.	
/AH/	27	4,861,590	08-29-1989	GRODBERG	
/AH/	28	4,863,743	09-05-1989	HSIAO, et al.	
/AH/	29	4,871,548	10-03-1989	EDGREN, et al.	
/AH/	30	4,882,167	11-21-1989	JANG	

Examiner Signature	/Alicia Hughes/	Date Considered	05/22/2010
--------------------	-----------------	-----------------	------------

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

IDS Form PTO/SB/08: Substitute for form 1449A/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Application Number	10/623,431
				Filing Date	July 18, 2003
				First Named Inventor	Jay D. KRANZLER
				Art Unit	1614
				Examiner Name	Alicia R. HUGHES
Sheet	2	of	4	Attorney Docket Number	11013.0012-00000

U.S. PATENTS AND PUBLISHED U.S. PATENT APPLICATIONS					
Examiner Initials ¹	Cite No. ¹	Document Number	Issue or Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
/AH/	31	4,892,742	01-09-1990	SHAH	
/AH/	32	5,464,633	11-07-1995	CONTE, et al.	
/AH/	33	5,472,708	12-05-1995	CHEN	
/AH/	34	5,512,297	04-30-1996	BAICHWAL	
/AH/	35	5,532,244	07-02-1996	WONG, et al.	
/AH/	36	5,532,250	07-02-1996	WONG, et al.	
/AH/	37	5,776,969	07-07-1998	JAMES	
/AH/	38	5,885,616	03-23-1999	HSIAO, et al.	
/AH/	39	6,066,643	05-23-2000	PERRY	
/AH/	40	6,380,200	04-30-2002	MYLARI	
/AH/	41	6,964,962	11-15-2005	WONG, et al.	
/AH/	42	7,005,452	02-28-2006	DEREGNAUCOURT, et al.	
/AH/	43	2007-0225375	09-27-2007	KRANZLER, et al.	
/AH/	44	2008-0034101	02-07-2008	TRAN, et al.	
/AH/	45	2008-0058317	03-06-2008	RAO, et al.	
/AH/	46	2008-0058318	03-06-2008	RAO, et al.	
/AH/	47	2008-0293820	11-27-2008	RAO, et al.	

Note: Submission of copies of U.S. Patents and published U.S. Patent Applications is not required.

FOREIGN PATENT DOCUMENTS						
Examiner Initials ¹	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Translation ⁶
		Country Code ³ Number ⁴ Kind Code ⁵ (if known)				
/AH/	48	CA 2,431,041	07-11-2002	Pharmacia & Upjohn Co.		
/AH/	49	WO 97/10816	03-27-1997	Eli Lilly		
/AH/	50	WO 03/053426	07-03-2003	Cypress BioScience		
/AH/	51	WO 2004/009069	01-29-2004	Cypress BioScience		
/AH/	52	WO 2004/030633	04-15-2004	Cypress BioScience		
/AH/	53	WO 2007/038620	04-05-2007	Cypress BioScience		
/AH/	54	WO 2008/019388	02-14-2008	Cypress BioScience		
/AH/	55	WO 2008/021932	02-21-2008	Cypress BioScience		

Examiner Signature	/Alicia Hughes/	Date Considered	05/22/2010
--------------------	-----------------	-----------------	------------

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

IDS Form PTO/SB/08: Substitute for form 1449A/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Application Number	10/623,431
				Filing Date	July 18, 2003
				First Named Inventor	Jay D. KRANZLER
				Art Unit	1614
				Examiner Name	Alicia R. HUGHES
Sheet	3	of	4	Attorney Docket Number	11013.0012-00000

NONPATENT LITERATURE DOCUMENTS				
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.		Translation ⁶
/AH/	56	AARON et al., "A review of the evidence for overlap among unexplained clinical conditions", Ann. Intern. Med. , Vol. 134, No. 9.2, (2001), pp. 868-881.		
/AH/	57	BOISSEVAIN et al., "Toward an integrated understanding of fibromyalgia syndrome. I. Medical and pathophysiological aspects", Pain, Vol. 45, No. 3, (1991), pp. 227-38.		
/AH/	58	BRILEY, "New hope in the treatment of painful symptoms in depression," Curr. Opin. Invest. Drugs, Vol. 4, No. 1, (2003), pp. 42-45. Abstract		
/AH/	59	GENDREAU et al., "Efficacy of Milnacipran in Patients with Fibromyalgia," The Journal of Rheumatology, Vol. 32, No. 10 (2005), pp. 1975-1984.		
/AH/	60	KASPER et al., "A placebo-controlled study of pregabalin and venlafaxine treatment of GAD", European neuropsychopharmacology, Vol.. 12, Suppl. 3, (October 2002), pp. S341-S342.		
/AH/	61	MEDLINE EMBASE 1998129084 1998 Milnacipran: New Preparation		
/AH/	62	MORET et al., "Sensitivity of the response of 5-HT autoreceptors to drugs modifying synaptic availability of 5-HT", Neuropharmacology, Vol. 27, No. 1, (1988), pp. 43-49.		
/AH/	63	WITTER et al., "Chronic pain and fibromyalgia: the regulatory perspective", Best Practice Res Clin Rheumatology, Vol. 17, No. 4, (2003), pp. 541-46		
/AH/	64	WOLFE et al., "A double-blind Placebo Controlled Trial of Fluoxetine in Fibromyalgia", Scand. J. Rheum., Vol. 23, No. 5, (1994), pp. 255-259.		
/AH/	65	WOLFE et al., "Health Status and Disease Severity in Fibromyalgia: Results of a Six-Center Longitudinal Study ", Arthritis Rheum., Vol. 40, No. 9, (1997), pp. 1571-1579		
/AH/	66	WOLFE et al., "Preference of Nonsteroidal Antiinflammatory Drugs Over Acetaminophen by Rheumatic Disease Patients", Arthritis Rheumatism, Vol. 43, No. 2, (2000), pp. 378-385.		
/AH/	67	WOLFE et al., "The American College of Rheumatology 1990 Criteria for the Classification of Fibromyalgia", Arthritis Rheumatism, Vol. 33, No. 2 (1990) pp. 160-172		
/AH/	68	WOLFE et al., "The Prevalence and Characteristics of Fibromyalgia in General Population", Arthritis Rheumatism, Vol. 38, No. 1 (1995) pp. 19-28.		
/AH/	69	YOSHIMURA et al., "The involvement of the tetrodotoxin-resistant sodium channel Nav1.8 (PN3/SNS) in a rat model of visceral pain", J. Neurosci., Vol. 21, No. 21, (2001), pp. 8690-8696.		
/AH/	70	PCT/US02/40976 (WO 03/053426), International Search Report dated May 2, 2003.		
/AH/	71	PCT/US02/40976 (WO 03/053426), International Preliminary Report on Patentability/Written Opinion dated November 15, 2003		
/AH/	72	PCT/US03/23088 (WO 2004/009069), International Search Report dated December 11, 2003.		
/AH/	73	PCT/US03/23088 (WO 2004/009069), International Preliminary Report on Patentability/Written Opinion dated May 3, 2005.		

Examiner Signature	/Alicia Hughes/	Date Considered	05/22/2010
--------------------	-----------------	-----------------	------------

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

IDS Form PTO/SB/08: Substitute for form 1449A/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Application Number	10/623,431
				Filing Date	July 18, 2003
				First Named Inventor	Jay D. KRANZLER
				Art Unit	1614
				Examiner Name	Alicia R. HUGHES
Sheet	4	of	4	Attorney Docket Number	11013.0012-00000

NONPATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.		Translation ⁶
/AH/	74	PCT/US03/031622 (WO 2004/030633), International Search Report dated June 3, 2004.		
/AH/	75	PCT/US03/031622 (WO 2004/030633), International Preliminary Report on Patentability/Written Opinion dated June 3, 2004.		
/AH/	76	PCT/US2006/037714 (WO 2007/038620), International Search Report dated August 23, 2007.		
/AH/	77	PCT/US2006/037714 (WO 2007/038620), International Preliminary Report on Patentability/Written Opinion dated April 1, 2008.		
/AH/	78	PCT/US2007/075555 (WO 2008/019388), International Search Report dated September 12, 2008.		
/AH/	79	PCT/US2007/075555 (WO 2008/019388), International Preliminary Report on Patentability/Written Opinion dated February 10, 2009.		
/AH/	80	PCT/US2007/075549 (WO 2008/021932), International Search Report dated September 19, 2008.		
/AH/	81	PCT/US2007/075549 (WO 2008/021932), International Preliminary Report on Patentability/Written Opinion dated February 10, 2009.		
/AH/	82	PCT/US2008/064471 (WO 2008/147843), International Search Report dated August 21, 2008.		
/AH/	83	PCT/US2008/064471 (WO 2008/147843), International Preliminary Report on Patentability/Written Opinion dated November 24, 2009.		
/AH/	84	U.S. Application No. 10/678,767, filed October 3, 2003, by Srinivas G. Rao et al.; Amendment accompanying request for continued examination dated September 3, 2009.		
/AH/	85	U.S. Application No. 10/678,767, filed October 3, 2003, by Srinivas G. Rao et al.; Non-Final Office Action dated January 8, 2010.		
/AH/	86	U.S. Application No. 11/535,237, filed Sept. 26, 2006, by Srinivas G. Rao et al.; Non-Final Office Action dated March 3, 2010.		
/AH/	87	U.S. Application No. 11/535,237, filed Sept. 26, 2006, by Srinivas G. Rao et al.; Restriction Requirement dated October 23, 2009.		
/AH/	88	U.S. Application No. 11/752,213, filed May 22, 2007, by Jay D. Kranzler et al.; Non-Final Office Action dated June 25, 2009.		
/AH/	89	U.S. Application No. 11/835,620, filed August 8, 2007, by Srinivas G. Rao et al.; Final Office Action dated July 2, 2009.		
/AH/	90	U.S. Application No. 12/035,820, filed February 22, 2008, by Jay D. Kranzler et al.; Final Office Action dated November 27, 2009.		
/AH/	91	U.S. Application No. 12/125,302, filed May 22, 2008, by Srinivas G. Rao et al.; Non-Final Office Action dated November 23, 2009.		

Examiner Signature	/Alicia Hughes/	Date Considered	05/22/2010
--------------------	-----------------	-----------------	------------

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.